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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,040	12/04/2001	Peter J. Klopotek	101646-0006	8441

21125 7590 08/20/2004

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EXAMINER	
MANTIS MERCADER, ELENI M	
ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 08/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,040	KLOPOTEK, PETER J.	
	Examiner	Art Unit	
	Eleni Mantis Mercader	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/13/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed have been fully considered but they are not persuasive. Applicant's amendments and arguments are not persuasive in that it is inherent that ultrasound propagates through tissue non-linearly. Therefore, all rejections are maintained and made final.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 21-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 6,325,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent alternate variations and groupings. The current claims appear to be broader in scope and thereby anticipated by the already patented claims.

3. Claims 21-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No.

6,113,559. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent alternate variations and groupings. The current claims appear to be broader in scope and thereby anticipated by the already patented claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 21-24, 27-29, 31-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Knowlton'380.

Regarding claims 21, 27, 29, and 33-35 Knowlton'380 teaches a method and an apparatus

for improving skin appearance by:

locating a target area of skin to be cosmetically enhanced including wrinkles(col. 1, lines 11-16; referring to contour sculpting of the skin and col. 1, lines 38-40; referring to the tightening of the skin to reduce aging effects);

introducing an amount of ultrasound thermal energy and propagating the ultrasound energy non-linearly into a dermis layer of the target area (col. 4, lines 38-43; referring to ultrasound heat energy application as an appropriate form of energy);

allowing the ultrasound energy to be absorbed by the dermis layer such that the dermis layer is stimulated or irritated sufficiently to induce new connective tissue formation (col. 4, lines 15-37; referring to application of the thermal radiant energy at a sufficient level to tighten the skin by partial denaturation of collagen); and

changing the smoothness of an epidermis layer of the skin (col. 1, lines 11-16; referring to contour sculpting of the skin and col. 1, lines 38-40; referring to the tightening of the skin to reduce aging effects);

and further having a control system for controlling the heat (i.e. ultrasound energy) applied in the dermal layer (see col. 3, lines 44-55 and col. 8, lines 47-67; note that the use of an acoustical waveguide is inherent whenever an ultrasound emitter is used).

Regarding claim 22, Knowlton'380 teaches applying a focused beam of the energy of interest (see col. 3, lines 44-60; and col. 6, lines 55-65).

Regarding claim 23, Knowlton'380 teaches application of ultrasonic energy (col. 4, lines 38-43; referring to ultrasound heat energy application as an appropriate form of energy) which inherently comprises acoustic pulses.

Regarding claims 24 and 31, Knowlton'380 teaches that the amount of ultrasound energy is effective to mechanically disrupt the dermis layer of the target area skin and delivering a spatially uniform dosage of ultrasound energy into the dermis (see col. 5, lines 1-23 and also see Figure 3; referring to the application of the energy at the dermis layer and breakage of the helix structures of the collagen or stated another way, mechanical disruption of the dermis layer).

Regarding claim 28, Knowlton'380 teaches the step of denaturing the proteins in the dermis layer (see col. 1, lines 56-65; describing the protein nature of collagen and col. 5, lines 1-12; referring to the denaturing of the collagen in the dermis layer).

Regarding claim 32, Knowlton'380 teaches the step of cooling the target area of the skin (see col. 4, lines 54-56).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knowlton'380 in view of Hutchinson et al.'971.

Knowlton'380 teaches all the features of the current invention except for the mechanical disruption of the dermis being done by shock waves or cavitation.

In the same field of endeavor, Hutchinson et al.'971 teaches shock waves or cavitation to treat an area of interest (see col. 2, lines 1-6).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Knowlton'380 and incorporated the teaching by Hutchinson et al.'971 in order to improve the energy deposition at the area of interest (see for motivation to combine Hutchinson et al.'971 in col. 1, lines 51-53).

8. Claims 30 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knowlton'380 in view of Lele'217.

Knowlton'380 teaches all the features of the current invention except for the step of scanning the beam of ultrasonic energy and wherein the ultrasound transducer is a phased array.

In the same field of endeavor, Lele'217 teaches scanning a phased array of ultrasound transducers to treat via hyperthermia the area of interest (see col. 2, lines 64-68 and col. 3, lines 1-50 and see Figure 1).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Knowlton'380 and incorporated the teaching by Lele'217 of scanning a phased array of ultrasound transducers in order to treat while utilizing uniform heating of the dermis layer (see for motivation to combine in Lele'217, col. 2, lines 50-58, describing the improvement of uniform heating).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eleni Mantis Mercader
Primary Examiner
Art Unit 3737

EMM